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Betreff: *Paroxetin* – hältige Arzneispezialitäten – Änderungen der Fach- und Gebrauchsinformationen aufgrund des HBD – PSUR Worksharing Projektes

Sehr geehrte Damen und Herren,

basierend auf der Evaluierung des PSURs im EU-HBD-worksharing Projekt (Verfahrensnummer: NL/H/PSUR/0023/004) kommt es zu der Empfehlung, folgende Ergänzungen in die **Fach- und Gebrauchsinformation** aller Paroxetin– hältigen Arzneispezialitäten aufzunehmen.

Sollten diese bereits aufgenommen worden sein, betrachten Sie dieses Schreiben als gegenstandslos.

Fachinformation

Section 4.4 Special Warnings and Special Precautions for use

Diabetes

In patients with diabetes, treatment with an SSRI may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted. Additionally, there have been studies suggesting that an increase in blood glucose levels may occur when paroxetine and pravastatin are co-administered. (see section 4.5)

→ Section 4.5 Interactions with other medicinal products and other forms of interaction

Pravastatin

An interaction between paroxetine and pravastatin has been observed in studies suggesting that co-administration of paroxetine and pravastatin may lead to an increase in blood glucose levels. Patients with diabetes mellitus receiving both paroxetine and pravastatin may require dosage adjustment of oral hypoglycaemic agents and/or insulin (see section 4.4).

→ Section 4.8 Undesirable Effects

Immune system disorders

Very rare: severe and potentially fatal allergic reactions (including **anaphylactoid reactions** urticaria and angioedema).



Metabolism and nutrition disorders

Uncommon: Altered glycaemic control has been reported in diabetic patients (see section 4.4).

Skin and subcutaneous tissue disorders

Common: sweating.

Uncommon: skin rashes, pruritus

Very rare: severe cutaneous adverse reactions (including erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis), urticaria, photosensitivity reactions.

Gebrauchsinformation

Section 2 What you need to know before you take 'Tradename'

Taking other medicines and 'TRADENAME'

Some medicines can affect the way 'TRADENAME' works, or make it more likely that you'll have side effects. 'TRADENAME' can also affect the way some other medicines work. These include:

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Metoprolol, a beta-blocker used to treat **high blood pressure** and **heart problems**

Pravastatin, used to treat **high cholesterol**

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Section 4 Possible side effects

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Very rare side effects, likely to affect up to 1 in every 10,000 people:

- **Allergic reactions, which may be severe to 'TRADENAME'.**

If you develop a red and lumpy skin rash, swelling of the eyelids, face, lips, mouth or tongue, start to itch or have difficulty breathing (shortness of breath) or swallowing and feel weak or lightheaded resulting in collapse or loss of consciousness, **contact your doctor or go to a hospital straight away.**

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Uncommon side effects, likely to affect up to 1 in every 100 people:

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An inability to urinate (urinary retention) or an uncontrollable, involuntary passing of urine (urinary incontinence)

If you are a diabetic patient you may notice a loss of control of your blood sugar levels whilst taking 'TRADENAME'. Please speak to your doctor about adjusting the dosage of your insulin or diabetes medications.

Oben angeführte Textabschnitte stellen eine Mindestanforderung dar, zusätzliche nationale Hinweise in diesen Abschnitten sind zu belassen.